

05-MAR-1998-0493

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FOR, ...

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Individual Safety Report

3847357-4-00

FDA on 11/15/93

Page ____ of ____

FDA use only

A. Patient information				C. Suspect medication(s)					
1. Patient Identifier In confidence	2. Age at time of event: or 8 yrs Date of birth:	3. Sex () female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 acetaminophen chewable tablets #2					
B. Adverse event or product problem				2. Dose, frequency & route used #1 "as recommended", po #2					
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown dates or duration #2					
2. Outcomes attributed to adverse event (check all that apply)				4. Diagnoses for use (indication) #1 stomach cramps #2					
() death (mo/day/yr) () life-threatening (X) hospitalization - initial or prolonged				5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No () N/A					
() disability () congenital anomaly () required intervention to prevent permanent impairment/damage () other:				6. Let # (if known) #1 Unknown #2					
3. Date of event (mo/day/yr) unknown		4. Date of this report (mo/day/yr) 02/13/98		7. Exp. date (if known) #1 Unknown #2		8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A			
5. Describe event or problem Report of LIVER DAMAGE, ENCEPHALOPATHY and PANCREATITIS in a 8 yo male w/ suspected child abuse. According to police investigator, the parents had given acetaminophen chewable tablets and DIMETAPP "as recommended"; duration was unknown. Reportedly the child was taken to the ER by parents because he had been experiencing stomach cramps & flu-like symptoms for over one month. The patient was transferred to 2nd hospital for care. MD diagnosed patient w/acetaminophen toxicity (OVERDOSE) based on an acetaminophen level of 77.7 mcg/ml drawn 15 hrs after admission to 2nd hospital. Pt was transferred to ICU & further diagnosed w/ pancreatitis, encephalopathy and 30% of liver cells were destroyed. Reportedly treatment was mostly unknown to reporter except that pt was put in a barbiturate coma. On 2/12/98, pt was weaned off barbiturates and removed from liver transplant list and continues to improve.				9. NDC # - for product problems only (if known) - -				10. Concomitant medical products and therapy dates (exclude treatment of event) DIMETAPP	
G. All manufacturers									
1. Contact office - name/address (& mailing site for devices) McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034				2. Phone number 215-233-7820					
4. Date received by manufacturer (mo/day/yr) 02/13/98				3. Report source (check all that apply) () foreign () study () literature () consumer () health professional () user facility () company representative () distributor (X) other: Police					
6. If IND, protocol #				(A) NDA # 17-552 IND # PLA # pre-1938 () Yes OTC product (X) Yes					
7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #				B. Adverse event term(s) OVERDOSE LIVER DAMAGE ENCEPHALOPATHY PANCREATITIS					
8. Relevant tests/laboratory data, including dates 15 hours post admission acetaminophen level=77.7 mcg/ml and the following day acetaminophen level=2 mcg/ml				9. Mfr. report number 0933572A					
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) hx of attention deficit disorder and one prior incident of child abuse				E. Initial reporter					
				1. Name, address & phone # [REDACTED]					
2. Health professional? () Yes (X) No		3. Occupation police investig		4. Initial reporter also sent report to FDA () Yes () No (X) Unk					



FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event